UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offic
ASSISTANT SECRETARY AND COMMISSIONER OF
PATENTS AND TRADEMARKS
Washington, D.C. 20231

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 13

Serial Number: 08/493,442
Filing Date: May 22, 1995
Appellant(s): Arter et al.

James J. Harrington
For Appellant

EXAMINER'S ANSWER

This is in response to Appellant's brief on appeal filed November 14, 1997.

(1) Real Party in Interest

The brief does not contain a statement identifying the Real Party in Interest. Therefore, it is presumed that the party named in the caption of the brief is the Real Party in Interest, i.e., the owner at the time the brief was filed. The Board, however, may exercise its discretion to require an explicit statement as to the Real Party in Interest.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

This appeal involves claims 9-11, 13-17.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after

final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 9-11, 13-17 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

4,675,290 Matsumoto et al. 6-1987

4,820,649 Kawaguchi et al. 4-1989

4,845,030 Batz et al. 7-1989

4,999,288 DeCastro et al. 3-1991

Hammond, P. Development of an Enzyme Based Assay for Acetaminophen. Analytical Biochemistry, Vol. 143, (1984), pp. 152-157.

Arter, T. Development of a Multilayered Colorimetric Assay for

Serum Acetaminophen. Clinical Chemistry, Vol. 39, No. 6 (1993), p. 1230.

(10) New Prior Art

No new prior art has been applied in this examiner's answer.

(11) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and

potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11, 14, 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Arter or Hammond in view of either Matsumoto or deCastro and in further view of Batz.

Arter (Clinical Chem dated July 1993) having different inventorship than this application, entitled "Development of a Multilayered Colorimetric Assay for Serum Acetaminophen," teaches in the abstract, a multilayered colorimetric assay using aryl acyl amidase to hydrolyze acetaminophen into p-aminophenol after application of serum to the slide. P-aminophenol formed is oxidized by either tyrosinase or by ascorbic acid oxidase so that it will form a dye with tetrahydroquinoline coupler. The dye is determined and is proportional to the amount of acetaminophen present.

Hammond (Analytical Biochemistry) entitled "Development of an Enzyme Based Assay for Acetaminophen" teaches on page 153 column 2, acetaminophen is enzymically hydrolyzed by aryl acylamide amidohydrolase to yield p-aminophenol and acetate. Then color reagents were studied with cyanoferrate complexes. On page 154 Table 1 teaches various color reactions and reagents.

The claims differ from Arter and Hammond in that they include a coupling agent with the color reagent and an oxidizing enzyme which couples to p-aminophenol, such as ascorbic acid

oxidase, lactase and tyrosinase.

Matsumoto (4,675,290) entitled "Assaying Peptidase Enzyme Activity" teaches an assay for enzyme activity which comprises reacting an amide compound with peptidase, and treating the liberated amine with a coupler, forming a colored pigment by means of oxidative condensation in the presence of an enzyme oxidant. The reaction scheme is as follows:

(1) Amide peptidase --> amine +

(2) Coupler Enzyme oxidant --> colored product.

In column 3 compound 4 a substrate for the enzyme, an amide, is shown which upon action of the peptidase yields an amine, compound 5. Compound 5 is converted to a chromogen by oxidative condensation of the coupler, compound 3 disclosed in column 4. The coupler is described as an aromatic compound which forms a chromogen having absorption maxima at 550-750 nm. The enzyme oxidants include ascorbate oxidase, tyrosinase in column 8 line 14. In column 8 line 49 through column 9 the aniline derivative forms a chromogen with a coupler, a cyanoferric compound. In column 10 first full paragraph, various cyanoferric complexes are shown.

deCastro (4,999,288) entitled Test Composition and Method for the Determination of Anilides" teaches determination of acetaminophen with stabilized arylacylamidase which cleaves the amide bond of acetaminophen, and reagents which act as oxidizing agents and accelerate color development.

The reaction scheme is as follows:

(1) Acetaminophen arylacylamidase --> 4-hydroxyaniline (amine)+

(2) Phenol derivative (coupler) catalyst/oxidant --> colored product.

deCastro teaches periodate as the catalyst/oxidant which enables color formation to take place in one step so that all reagents can be added to the sample in one step which makes it possible to develop, dip and read test strips containing all the necessary reagents needed for testing an anilide.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the oxidizing enzyme and coupling agents of Matsumoto and deCastro in the determination of Arter and Hammond because the reactions employed for the determinations are nearly identical and Matsumoto and deCastro provide motivation for employing coupling agents and oxidizing enzymes. To employ coupling agents to enhance color formation is well known in this art and is employed in the presently claimed invention for its art recognized function. Both Matsumoto and deCastro employ oxidizing agents and enzymes for the same function as presently claimed.

The present claims further differ from the above references in that they are directed to specific coupling agent compounds which encompass 1-(3-sulfopropyl)-1,2,3,4-tetrahydroquinoline.

Batz (4,845,030) entitled "Use of Aniline Derivatives As Coupling Components In Oxidative Color Formation Reactions" teaches in column 2, structure I which encompasses the presently claimed coupling agent, 1-(3-sulfopropyl)-1,2,3,4-tetrahydroquinoline. The aniline derivatives of Batz are shown to have substantially improved color stability and a lower blank creep in oxidative coupling reactions. Substitutions with polar groups show an improved solubility and groups such as alkylsulfonic acid or sulfonic acid groups show good water solubility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the specific coupling agent of Batz in the determinations of Arter, Hammond, Matsumoto and deCastro because Matsumoto and deCastro teach closely related coupling agents for the same function as presently claimed. One would have a high expectation of success in substituting a known coupling agent for any of a large group of coupling agents in view of Batz because Batz teaches the presently claimed coupling agent for the same function as presently claimed.

Claims 13, 15 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Arter or Hammond in view of either Matsumoto or deCastro and in further view of Batz as applied to claims 9-11, 14, 17 above, and further in view of

Kawaguchi.

The teachings of Arter, Hammond, Matsumoto, deCastro and Batz and their applicability to the instant invention have been discussed above.

The claims differ from the above references in that the element contains maleimide in the spreading layer.

Kawaguchi (4,820,649) entitled "Method and Kit Having Layered Device for Detecting Biological Component by Interference Color" teaches in column 17 lines 22, column 18 first full paragraph, column 18 lines 32-33, maleimide groups are employed in layered detection devices and related to interferences.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the maleimide of Kawaguchi in the test strips of the above references because the maleimide would have its expected function, reducing interferences.

(12) New Ground of Rejection

This examiner's answer does not contain any new ground of rejection.

(13) Response to argument

Appellants argue that Arter does not teach ferricyanide and a coupler, Kawaguchi does not teach the claimed maleimide, Hammond teaches a different pH range than that claimed, Matsumoto does not teach a coupler, deCastro does not teach gelatin or ferricyanide, Batz does not teach dry analytical elements,

coupler or ferricyanide. The present invention avoids the problem of gelatin hardening and permits a rapid determination.

It is the examiner's position that each of the above references were cited to show the features discussed above. Arter teaches a dry element, Hammond teaches the present reaction, Matsumoto teaches couplers and cyanoferric compounds, deCastro teaches oxidizing agents, Batz teaches coupling agents, Kawaguchi teaches maleimide. Appellant's failure to consider the references together is inappropriate in view of the fact that the rejection was made under 35 U.S.C. § 103, on the basis of what the combined teachings of the references would have suggested to one of ordinary skill in the relevant art, and not under 35 U.S.C. § 102, on the basis of anticipation by any of the individual references.

The present claims do not contain limitations regarding hardening of gelatin or determination times. It is respectfully submitted that in order for evidence of unexpected results to be sufficient to rebut a prima facie case of obviousness, the evidence must be commensurate in scope with the claims.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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